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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,860	07/23/2003	Dale N. Larson	36373-012	7992

7590 04/17/2007  
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EXAMINER
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BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
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1744

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/625,860

Applicant(s)

LARSON ET AL.

Examiner

Nathan A. Bowers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-16 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-16 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 1) Claims 1, 8, 9 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "small" in claims 1 and 12 is a relative term which renders the claim indefinite. The term "small" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Essentially any object of any size could be considered "small" in the absence of appropriate guidelines.

With respect to claims 8 and 9, line 2 of claim 8 indicates that the "small objects comprise one or more living organisms." However, the small objects are defined as affinity beads in claim 1. Affinity beads are not living organisms.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- 2) Claims 1, 3-16 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Frondoza (US 20050147959).

Frondoza discloses an apparatus for intermixing small objects with a liquid comprising a plurality of receptacle wells (Figure 1:3) containing the small objects. Each of the wells has a lower portion (Figure 1:4) that is permeable to permit the flow of liquid therethrough. A vessel (Figure 1:5) containing a solution is also provided, as well as means for repeatedly inserting the receptacles into the solution held in the vessel. The receptacle can then be withdrawn to cause the liquid to flow outwardly through the lower portion while retaining the small objects. This is disclosed in paragraphs [0037]-[0052] and [0064]-[0073]. Specifically, Frondoza teaches in paragraphs [0051] and [0052] that the small objects comprise cells cultured upon microcarriers. Paragraphs [0064]-[0073] further indicate that the cells are subjected to pharmaceuticals in order to study their affects on the activity and health of the cells.

- 3) Claims 1, 3-7, 10-16 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Feygin (US 6315957).

Feygin discloses an apparatus for intermixing small objects with a liquid comprising a plurality of receptacles (Figure 2:222) having a lower portion (Figure 2:226) that is permeable to permit the flow of liquid therethrough. A vessel (Figure 3:330) is additionally provided for containing a solution. The receptacles are repeatedly inserted into the solution held by the vessel in order to allow the solution to permeate through the pores located at the lower portions of the receptacles. The pores are sized so that they allow the passage of fluids, but not the passage of

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the small objects. This is disclosed in column 1, line 58 to column 2, line 38 and column 3, line 15 to column 4, line 19. Means for repeatedly moving the receptacle in and out of the vessel are described in column 4, line 53 to column 5, line 21 and in Figure 5.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4) Claims 1, 3-7, 10-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feygin (US 6315957) in view of Reeve (WO 9112079) and/or Valkirs (US 6348318).

Feygin discloses the described in the previous rejections above. In addition, Feygin discloses in column 6, lines 10-20 that affinity beads are used as small objects that facilitate a reaction with the solution as it moves through the permeable bottom of the receptacle from the vessel. Feygin, however, does not expressly state that the liquid solution is a lysate that contains proteins that become bound to the affinity beads when the solution and the affinity beads are intermixed.

Reeve discloses a method of purifying proteins. Reeve indicates on pages 4-6 that it is known in the art to remove proteins from a cell lysate by allowing them to bind to the surfaces of a plurality of affinity beads.

Valkirs discloses a method that involves the use of affinity beads that selectively bind to protein analytes in solution. The surfaces of the beads are covered with a moiety that attaches to analytes in order to form a target complex. The beads can then be removed from the solution as a means by which to obtain a purified product. This is disclosed in column 1, line 52 to column 2, line 52.

Feygin, Reeve and Valkirs are analogous art because they are from the same field of endeavor regarding filtering and protein purification systems.

At the time of the invention, it would have been obvious to use the device proposed by Feygin in order to purify protein analytes in a lysate solution. Feygin already teaches that the device is capable of allowing particles in a solution to move through the porous bottom of the

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receptacle in order to interact with solid support beads. Therefore, one skilled in the art would have been fully capable of implementing the ideas regarding protein purification disclosed by Reeve and/or Valkirs in order to create a system in which the receptacle is allowed to interact with a lysate solution and remove protein targets. Absent a showing of criticality, it would have been obvious to utilize the affinity beads disclosed by Feygin as a means by which to bind to proteins in a lysate that are allowed to filter through a permeable barrier, especially since Reeve and Valkirs indicate that this is an effective process that is known in the art.

#### *Response to Arguments*

In response to Applicant's remarks, the rejection involving the Feygin reference is now made under 35 U.S.C. 102(e) rather than 35 U.S.C. 102(b).

Applicant's arguments filed 10 January 2007 with respect to the 35 U.S.C. 112 rejections have been fully considered but they are not persuasive. Even though Applicant has amended the claims to define the small objects as affinity beads, the claims remain indefinite. Affinity beads are constructed in a range of sizes in the art. A specified affinity bead may be simultaneously considered small and large when compared to other affinity beads.

Applicant's arguments filed 10 January 2007 with respect to the 35 U.S.C. 102 rejections involving the Shimazaki reference have been fully considered and are persuasive. These rejections have been withdrawn.

Applicant's arguments filed 10 January 2007 with regard to the 35 U.S.C. 102 rejections involving the Frondoza and Feygin references have been fully considered but they are not persuasive.

*Applicant's principle arguments are*

*(a) Frondoza and Feygin do not show an apparatus for purification of proteins.*

*Frondoza and Feygin fail to show any affinity beads, and do not disclose that the liquid is a lysate containing proteins to be purified.*

In response to Applicant's arguments, please consider the following comments.

Applicant is assigning undue weight to various phrases presented in the claims that communicate an intended use. Phrases such as "for intermixing small objects and a liquid" and "for receiving and retaining said small objects" are merely intended use phrases, and therefore do are not given significant weight during prosecution of apparatus claims. Frondoza and Feygin each disclose (1) a receptacle, (2) a permeable portion of the receptacle, (3) a vessel capable of accommodating the receptacle, and therefore disclose all of the *structural* features presented in the claims. Since both references disclose that the permeable portions include orifices with micron-scale diameters, it must be concluded that the references are capable of practicing the claimed intended use.

In response to applicant's argument that the prior art does not describe steps in which affinity beads are intermixed with a lysate, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.



Applicant states that the instant invention is patentable over Frondoza and Feygin because the receptacle of the claimed invention holds a lysate containing proteins (Frondoza and Feygin do disclose receptacles, but do not disclose lysates containing proteins). Applicant's argument is analogous to an argument that a claimed automobile comprising a fuel tank containing only gasoline is patentably distinct from a prior art automobile that is structurally the same in all respects but has a fuel tank containing 90% gasoline and 10% ethanol. Clearly, such a distinction is not patentable under current patent jurisprudence.

Applicant's arguments filed 10 January 2007 with regard to the 35 U.S.C. 103 rejections involving the combination Feygin with Reeve and/or Valkirs have been fully considered but they are not persuasive.

*Applicant's principle arguments are*

*(a) The separation of Reeve and Valkirs is based on entirely different technology than the separation system of the present claims. The separation of these references requires magnetically attractable beads and application of a magnetic field, which is completely different than filtration. Accordingly, the proposed combination would not result in the presently claimed invention.*

In response to Applicant's arguments, please consider the following comments.

Applicant lists several possible combinations on page 17 of the Remarks in an effort to show that the combined references are incapable of producing the claimed apparatus. In doing so, Applicant seems to ignore the proposed combination that is described in the previous and current Office Actions. The Feygin reference clearly discloses all of the structural features of the

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claimed invention regarding the receptacle, permeable portion, and vessel. The permeable portion of Feygin is microns in size, and therefore entirely capable of being used to filter affinity beads from a liquid sample. Therefore, one would not be motivated to alter the structure of Feygin when applying the Reeve and Valkirs references. The Reeve and Valkirs references are merely presented as evidence to show that separation of proteins from a lysate using affinity beads is well known in the art. The Reeve and Valkirs references would not persuade one from altering the filtration method set forth by Feygin (in favor of other methods, such as those that rely on magnetic fields), but rather would encourage one of ordinary skill in the art to use the disclosed filtration method to separate other types of small objects besides the ones disclosed by Feygin. Since protein purification is such an important aspect of many biological analytical procedures, it would have been obvious to utilize the apparatus of Feygin to purify proteins through the separation of affinity beads.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

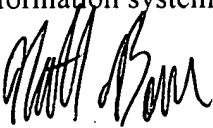
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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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